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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,276	12/22/1999	RICHARD KOLODNER	157/47483-C	5964

7590 01/06/2003

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EXAMINER
FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
1637	27

DATE MAILED: 01/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/470,276	KOLODNER ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,6-8,10,12 and 39-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2,4,12,29,40 and 42-45* is/are allowed.

6)☒ Claim(s) *3,6-8,10,41 and 46-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 26, 2002 has been entered.

General

2. Claim 3 utilizes the transitional term "containing". Because this term lacks any particular meaning in the patent literature, the examiner will interpret "containing" as being equivalent in scope to the open term "comprising".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 3, 6, 8, 41, 48 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al (Genbank Accession No. T67203).

Hillier teaches a nucleic acid sequence which is an 303 nucleotide isolated nucleotide segment that is less than 3000 nucleotides and that contains a fragment of at least 25 contiguous nucleotides from the coding region of SEQ ID NO: 1 as shown in

the alignment below. In particular, the coding region of SEQ ID NO: 1 extends from nucleotides 235 to 2737 (see response by Applicant, paper No. 20). The Hillier sequence extends from nucleotides 2582 to 2737, representing a sequence comprising 156 nucleotides of the coding sequence of SEQ ID NO: 1. Hillier further teaches that the isolated nucleic acid was in a vector in a host cell, specifically a DH10B library (see lab host).

```
  Query Match             10.4%;  Score 303;  DB 14;  Length 466;
  Best Local Similarity   100.0%;  Pred. No. 3.9e-62;
  Matches  303;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy    2582 CCATCAAGCCTGTCAAGGATTTGCTAAAGAAGAACCAAATGGAAAATTGCCAGACATTAG 2641
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1 CCATCAAGCCTGTCAAGGATTTGCTAAAGAAGAACCAAATGGAAAATTGCCAGACATTAG 60

Qy    2642 TGGATAAGTTTATGAAACTGGATTTGGAAGATCCTAACCTGGACTTGAACGTTTTCATGA 2701
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 TGGATAAGTTTATGAAACTGGATTTGGAAGATCCTAACCTGGACTTGAACGTTTTCATGA 120

Qy    2702 GCCAGGAAGTGCTGCCTGCTGCCACCAGCATCCTCTGAGAGTCCTTCCAGTGTCCTCCCC 2761
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 GCCAGGAAGTGCTGCCTGCTGCCACCAGCATCCTCTGAGAGTCCTTCCAGTGTCCTCCCC 180

Qy    2762 AGCCTCCTGAGACTCCGGTGGGCTGCCATGCCCTCTTTGTTTCCTTATCTCCCTCAGACG 2821
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     181 AGCCTCCTGAGACTCCGGTGGGCTGCCATGCCCTCTTTGTTTCCTTATCTCCCTCAGACG 240

Qy    2822 CAGAGTTTTTAGTTTCTCTAGAAATTTTGTTTCATATTAGGAATAAAGTTTATTTTGAAG 2881
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     241 CAGAGTTTTTAGTTTCTCTAGAAATTTTGTTTCATATTAGGAATAAAGTTTATTTTGAAG 300

Qy    2882 AAA 2884
           |||
Db     301 AAA 303
```

5. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Promega catalog (1993/94) p. 166.

The Promega catalog teaches a kit with a set of DNA primers which permit synthesis of the coding sequence of hMSH5, specifically the random hexameric primers (p. 166).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier as applied to claims 3 and 6 in view of Vanin et al (U.S. Patent 5,710,037).

Hillier teaches a nucleic acid sequence which is an 303 nucleotide isolated nucleotide segment that is less than 3000 nucleotides and that contains a fragment of at least 25 contiguous nucleotides from the coding region of SEQ ID NO: 1 as shown in the alignment below. In particular, the coding region of SEQ ID NO: 1 extends from nucleotides 235 to 2737 (see response by Applicant, paper No. 20). The Hillier sequence extends from nucleotides 2582 to 2737, representing a sequence comprising 156 nucleotides of the coding sequence of SEQ ID NO: 1. Hillier further teaches that

the isolated nucleic acid was in a vector in a host cell, specifically a DH10B library (see lab host).

```
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  Best Local Similarity   100.0%;  Pred. No. 3.9e-62;
  Matches  303;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy    2582 CCATCAAGCCTGTCAAGGATTTGCTAAAGAAGAACCAAATGGAAAATTGCCAGACATTAG 2641
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1 CCATCAAGCCTGTCAAGGATTTGCTAAAGAAGAACCAAATGGAAAATTGCCAGACATTAG 60

Qy    2642 TGGATAAGTTTATGAAACTGGATTTGGAAGATCCTAACCTGGACTTGAACGTTTTCATGA 2701
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 TGGATAAGTTTATGAAACTGGATTTGGAAGATCCTAACCTGGACTTGAACGTTTTCATGA 120

Qy    2702 GCCAGGAAGTGCTGCCTGCTGCCACCAGCATCCTCTGAGAGTCCTTCCAGTGTCCTCCCC 2761
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 GCCAGGAAGTGCTGCCTGCTGCCACCAGCATCCTCTGAGAGTCCTTCCAGTGTCCTCCCC 180

Qy    2762 AGCCTCCTGAGACTCCGGTGGGCTGCCATGCCCTCTTTGTTTCCTTATCTCCCTCAGACG 2821
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     181 AGCCTCCTGAGACTCCGGTGGGCTGCCATGCCCTCTTTGTTTCCTTATCTCCCTCAGACG 240

Qy    2822 CAGAGTTTTTAGTTTCTCTAGAAATTTTGTTTCATATTAGGAATAAAGTTTATTTTGAAG 2881
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     241 CAGAGTTTTTAGTTTCTCTAGAAATTTTGTTTCATATTAGGAATAAAGTTTATTTTGAAG 300

Qy    2882 AAA 2884
           |||
Db     301 AAA 303
```

Hillier does not teach placement of the sequence into a retroviral vector.

Vanin teaches placement of genes of interest into retroviral vectors (column 3, lines 18-45).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to utilize the retroviral vector of Vanin to express the EST of Hillier since Vanin states "Attractive features of retroviral vectors include flexibility, that is the variety of coding sequences that can be transferred, high although variable transduction efficiency, and stability of the proviral genome once integrated into a host cell chromosome (column 1, lines 21-24)". An ordinary practitioner would have been motivated to clone the EST of Hillier into a retroviral vector as taught by Vanin since the vector is flexible, stable and has high transduction efficiency.

9. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al as applied to claims 3 and 41 in view of Dattagupta et al (EP 297,379).

Hillier teaches a nucleic acid sequence which is an 303 nucleotide isolated nucleotide segment that is less than 3000 nucleotides and that contains a fragment of at least 25 contiguous nucleotides from the coding region of SEQ ID NO: 1 as shown in the alignment below. In particular, the coding region of SEQ ID NO: 1 extends from nucleotides 235 to 2737 (see response by Applicant, paper No. 20). The Hillier sequence extends from nucleotides 2582 to 2737, representing a sequence comprising 156 nucleotides of the coding sequence of SEQ ID NO: 1. Hillier further teaches that the isolated nucleic acid was in a vector in a host cell, specifically a DH10B library (see lab host).

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Query Match             10.4%;  Score 303;  DB 14;  Length 466;
Best Local Similarity   100.0%;  Pred. No. 3.9e-62;
Matches  303;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy    2582 CCATCAAGCCTGTCAAGGATTTGCTAAAGAAGAACCAAATGGAAAATTGCCAGACATTAG 2641
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db       1 CCATCAAGCCTGTCAAGGATTTGCTAAAGAAGAACCAAATGGAAAATTGCCAGACATTAG 60

Qy    2642 TGGATAAGTTTATGAAACTGGATTTGGAAGATCCTAACCTGGACTTGAACGTTTTCATGA 2701
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      61 TGGATAAGTTTATGAAACTGGATTTGGAAGATCCTAACCTGGACTTGAACGTTTTCATGA 120

Qy    2702 GCCAGGAAGTGCTGCCTGCTGCCACCAGCATCCTCTGAGAGTCCTTCCAGTGTCCTCCCC 2761
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     121 GCCAGGAAGTGCTGCCTGCTGCCACCAGCATCCTCTGAGAGTCCTTCCAGTGTCCTCCCC 180

Qy    2762 AGCCTCCTGAGACTCCGGTGGGCTGCCATGCCCTCTTTGTTTCCTTATCTCCCTCAGACG 2821
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     181 AGCCTCCTGAGACTCCGGTGGGCTGCCATGCCCTCTTTGTTTCCTTATCTCCCTCAGACG 240

Qy    2822 CAGAGTTTTTAGTTTCTCTAGAAATTTTGTTTCATATTAGGAATAAAGTTTATTTTGAAG 2881
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     241 CAGAGTTTTTAGTTTCTCTAGAAATTTTGTTTCATATTAGGAATAAAGTTTATTTTGAAG 300

Qy    2882 AAA 2884
           |||
Db     301 AAA 303
```

Hillier does not teach labeling the nucleic acid.

Dattagupta teaches the use of fluorescence labels (column 9, lines 25-31).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the nucleic acid of Hillier with the fluorescent labels of Dattagupta since Dattagupta states "the incorporation of labels will be the direct indication of the specific processes and hence the presence of a specific test sequence (column 9, lines 27-30)". An ordinary practitioner would have been motivated to use the fluorescent labels of Dattagupta with the nucleic acid of Hillier for the stated benefit of identifying a specific target sequence and the expected benefits of sensitivity and specificity known in the art to result from fluorescent labels.

Allowable Subject Matter

10. Claims 2, 4, 12, 39, 40, 42, 43, 44 and 45 are allowed.

11. The following is a statement of reasons for the indication of allowable subject matter: The claimed sequences are novel and unobvious over the cited prior art.

Response to Arguments

12. Applicant's arguments filed November 26, 2002 have been fully considered but they are not persuasive.

With regard to the new Hillier rejections, Applicant's arguments are moot, since they are drawn to rejections which are no longer applicable and which are withdrawn.

With regard to the Promega catalog rejection, Applicant argues that the primers are selected from the isolated segments of claim 3. This statement is not correct. Claim 10 does not refer to claim 3 in any way and is an independent claim. The

hexamer primers would achieve the only functional result required by claim 10 and consequently anticipate the claim. This rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1637

January 3, 2003